REMARKS/ARGUMENTS

I. Amendment to the Specification

Paragraphs [00102] and [00104] are amended to change "a base separation means" to "a base separating means" to improve wording and to match a similar amendment in the claims.

Paragraph [00123] is amended to replace the "base separating means" with the "base securing means", and to correct spelling. Support is found in Claims 5-11 as originally filed.

II. Amendment to the Claims

Claims 1-11 and 16-22 are in the application. Claims 12-15 are canceled. Claims 1, 5, 6, 9, 10 and 17-21 are amended.

Claim 1 is amended to improve the wording of the terms, and to obviate an indefiniteness rejection of the claim, and to provide that the needle moveable between a first position having its injection end wholly within the housing, and a second position wherein the injection end extends through and beyond the base portion, as support in paragraph [0068].

Claim 5, 6, 9, 17, 18 and 22 are amended to improve the wording or to correct antecedent basis.

Claim 10 is amended to provide the "needle retracting means" to correct antecedent basis to Claim 1, to identify a needle insertion securement as a structural element of the needle retracting means, and to change "a needle retraction means" to "a power means", for biasing the needle toward a position within the housing. Support is found in paragraph [00116].

Claim 19 is amended to provide antecedent basis for the at least one engaging member, that can be biased to a second position wherein the removable base is not secured to the housing.

Claim 20 is amended to improve the wording and obviate an indefiniteness rejection of the claim.

Claim 21 is amended to provide the "needle retracting means" to correct antecedent basis to Claim 1, and to rephrase the claim wording as supported in paragraph [00104].

No new claims fees are believed due, and all claim amendments are supported by the originally-filed specification.

III. Objections to the Claims

Claims 5, 6, 10, 17, 21 are objected to because of the following informalities: "the means for separably affixing" (claims 5, 6) lacks antecedent basis; "the retracting means" (claims 10 and 21) lacks antecedent basis; "the needle retraction means" (claim 21) lacks antecedent basis; "the injection means" (claim 17) lacks antecedent basis. Appropriate correction is indicated as required.

With respect to "the means for separably affixing" in Claims 5 and 6, Claims 1 is amended to provide a "means for separably securing the separable base", obviate the objection.

With respect to "the retracting means", Claims 10 and 21 are amended to "the needle retracting means" and find self-evident antecedent basis in Claim 9 and 20, respectively.

With respect to the "needle retraction means", Claim 21 is amended to obviate the objection.

With respect to the "injection means", Claim 17 does not include the phrase "injection means"; however, Claim 17 does include an additional feature "a means for injecting the vaccine".

IV. Rejections under 35 USC §112

Claims 1-11 and 16-22 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

The rejection states that in claims 1, 17, and 20, the written description fails to clearly link or associate the disclosed structure, material, or acts to the claimed function "*comprising an adhesive on a skin facing surface thereof and an opposed surface*".

Applicants request reconsideration. Claims 1 and 20 are amended to correct the deficiency.

The rejection states that in claim 19, the phrase "the at least one engaging member cannot be biased to its second position unless the needle is at its housing position".

Applicants request reconsideration. Claim 19 are amended to correct the deficiency.

The rejection states that in claims 1, 17, and 20, the written description fails to clearly link or associate the disclosed structure, material, or acts to the claimed function *"means for injecting a vaccine from the reservoir through the needle"*, identified as the injecting measn in Claim 17.

Applicants request reconsideration. Paragraph [00101] identifies to a person of ordinary skill the corresponding structure that performs the claimed function. The corresponding structure that performs the claimed function of "injecting a vaccine from the reservoir through the needle" and "the injecting means" is set forth in the written description of the specification at paragraph [00101].

The rejection states that in claims 1 and 20, the written description fails to clearly link or associate the disclosed structure, material, or acts to the claimed function *"means for separably affixing the separable base with the base portion"*.

Applicants request reconsideration. Applicants have amended in Claim 1 and 20 "means for separably affixing the separable base" to "means for separably securing the separable base", to more clearly claim the features. Paragraphs [00101] – [00103], and paragraph [00123] set forth the corresponding structure that performs the claimed function of a "base securement means", which is the means for separably securing the separable base to the housing.

The rejection states that in claims 1 and 22, the written description fails to clearly link or associate the disclosed structure, material, or acts to the claimed function *"means for selectively separating the separable base from the device while the separable base is secured to the skin"*.

Applicants request reconsideration. Paragraphs [00102], [00104] and paragraph [00123] set forth the corresponding structure that performs the claimed function of a "base securement means", which is the means for separably securing the separable base to the housing.

The rejection states that in claims 9, 10, 18, 20 and 21, the written description fails to clearly link or associate the disclosed structure, material, or acts to the claimed function *"means for retracting the injection needle "*.

Applicants request reconsideration. Paragraph [00116], and well as paragraphs [0066]-

[0070], set forth the corresponding structure that performs the claimed function of the "needle retracting means".

The rejection states that in claim 10, the written description fails to clearly link or associate the disclosed structure, material, or acts to the claimed function *"means for moving a needle insertion securement..."*.

Applicants request reconsideration in view of the amendment to Claim 10.

V. Rejections under 35 USC §103(a)

Claims 1, 2, 4-6, 16, and 18-22 are rejected under 35 U.S.C. 103(a) as being unpatentable over Miskinyar (US 5527287) in view of Woehr et al. (US 20030144627).

Applicants traverse.

The Examiner has the initial burden to set forth the basis for any rejection so as to put the patent applicant on notice of the reasons why the applicant is not entitled to a patent on the claim scope that he seeks – the "*prima facie* case." *In re Oetiker*, 977 F.2d 1443, 1445 (Fed. Cir. 1992); *In re Piasecki*, 745 F.2d 1468, 1472 (Fed. Cir. 1984) (the initial burden of proof is on the USPTO "to produce the factual basis for its rejection of an application under sections 102 and 103"). (emphasis added, quoting *In re Warner*, 379 F.2d 1011, 1016 (CCPA 1967)). Applicant's rebuttal evidence "may relate to any of the *Graham* factors including the so-called secondary considerations." The examiner then determines patentability "on the totality of the record, by a preponderance of the evidence with due consideration to the persuasiveness of argument."

An applicant can obviate an alleged *prima facie* obviousness rejection by submitting arguments and/or evidence to show that the examiner made an error in either (1) an underlying finding of fact upon which the final conclusion of obviousness was based, or (2) the reasoning used to reach the legal conclusion of obviousness. "[R]ejections on obviousness grounds cannot be sustained by mere conclusory statements; instead, there must be some articulated reasoning with some rational underpinning to support the legal conclusion of obviousness." *In re Kahn*, 441 F.3d 977, 988 (Fed. Cir. 2006), *cited with approval in KSR*, 550 U.S. at 418.

The recitation in the rejection of the alleged teaching of Miskinyar amounts to a copying word-by-word of Applicants' claim 1, and the insertion of reference numbers and figures out of

Miskinyar. Applicants assert that even a cursory look at the device and features described in Miskinyar informs one that they are no so literally the same as that of the claimed device, that an examiner can rely entirely on Applicants' own claim language to establish the record for the teaching of the prior art. The rejection *per se* fails to establish a *prima facie* case.

As an example of the inherent failing of the rejection, the examiner alleges that Miskinyar teaches "a separable base associated with the base portion" of the housing, as element 90, presumably of Figure 8 or 9 of Miskinyar. In Figure 8 of Miskinyar, a device (82) is shown having a housing (84) with an outer wall (86) and a bottom wall (90). The outer wall (86) and the bottom wall (90) are integrally formed with the housing (84). Miskinyar can not remotely be construed as teaching a separable base, as that claim term would be reasonably constructed in light of applicants' specification.

Further, a careful analysis of the device of Miskinyar would reveal the absence of other elements and features of the claimed invention, including a means for separably affixing (or securing) the separable base to the base portion of the housing, and a base separation (separating) means for selectively separating the separable base from the device while the separable base is secured to the skin.

Applicants' claims are to be given their "broadest reasonable construction in light of the specification of the patent or application in which it appears". Applicants assert that there is no reasonable construction of the claims that would permit each element and feature of the claims to be found in Miskinyar or any of the other references cited in combination therewith.

Although the rejection is of Claims 1, 2, 4-6, 16 and 18-22, Applicants also note that the examiner only addresses elements and features featured in Claims 1, 2, 6, 18, 20 and 22. For example, there is no mention in the rejection (or in Miskinyar) of: an adhesive flap that extends from the entire periphery of the separable base (claim 4); an engaging member that cannot be biased to a second position unless the needle is at its position within the housing (claim 19); and a means for retracting the injection needle (claim 20 and 21).

The rejection also fails to provide a *prima facie* case of obviousness because it fails to provide a rational basis to combine the teachings of Woehr et al with Miskinyar. The rejection states that it would be obvious to modify Miskinyar with Woehr et al "for the purpose of

providing a needle of sufficiently sized diameter to require an appropriate application of strength for use". This statement lacks rationale.

Woehr et al teaches a unique hypodermic needle assembly having a needle shield that can be retracted from blocking the hypodermic needle tip. Woehr et al disclose a list of the international standards for push and pull strengths that a needle and hub must provide based on a needle's outer diameter (Table 1). The set of needle sizes described in Table 1 of Woehr et al do not represent a set of needles that inherently provide for painless needle insertion into the skin across the full range of sizes. A few of the sizes may, but most do not. The rationale provided by the Examiner, as motivation for combining the McConnell-Montalvo and Woehr et al references, is not understandable, and if it cannot be understood and lacks rationale, it cannot form the basis for a *prima facie* rejection. Some objective (and rational) reason to combine the teachings of the references is required. ["A statement that modifications of the prior art to meet the claimed invention would have been 'well within the ordinary skill of the art at the time the claimed invention was made' because the references relied upon teach that all aspects of the claimed invention were individually known in the art, is not sufficient to establish a *prima facie* case of obviousness without some objective reason to combine the teachings of the references." *Ex parte Levengood*, 28 USPQ2d 1300 (Bd. Pat. App. & Inter. 1993).]

Furthermore, Woehr et al do not describe expressly the use of any particular needle size, and provide no teaching or suggestion of the problem of pain caused by the use of larger-diameter sized needles during intramuscular needle insertion. Consequently, while it may be possible that the device of Miskinyar could be modified by using one of the needles of any size shown in the Table 1 of Woehr et al, such mere possibility does not make the modification obvious unless the prior art suggested the desirability of the modification *(see In re Gordon, 733 F.2d 900, 902, 221 USPQ 1125, 1127 (Fed. Cir. 1984))*. Neither Miskinyar nor Woehr et al recognize, discuss or would suggest the benefit of a painless needle insertion, involving the appropriately sized needle defined by Applicants.

Claims 1, 2, 4-6, 16, and 18-22 are rejected under 35 U.S.C. 103(a) as being unpatentable over Miskinyar (US 5527287) in view of Woehr et al. (US 20030144627), and further in view of Hunn et al. (US 20040158207).

Applicants traverse.

The device described in Hunn et al is an infusion set. Hunn et al use the needle 8 only as an insertion means for the infusion tube 3, and that a separate plug 9 of the liquid supply device (Fig. 1) is affixed to the base and body 1,2 for infusion of the liquid. The rejection suggests that the combination would be obvious "for the purpose of improving the adhesion of the device to the injection site by increasing the surface area coated with adhesive". A person of ordinary skill would appreciate that infusion and injection are quite different methods, and would not find in either Miskinyar or Woehr et al any rational basis for combining the references, or any basis for concluding that "an improvement in adhesion of the device" is either needed or useful, or that "increasing the surface area coated with adhesive" would be the needed solution.

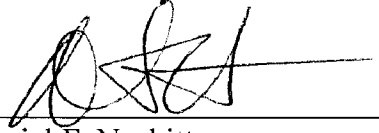
Finally, Applicants note that Claims 7-11 and 17, in addition to claims 4, 19, 20 and 21 mentioned beforehand, have not been rejected based upon art. .

Conclusion

Applicant believes a complete response to the office action has been provided, and that the present invention as claimed clearly distinguishes the teachings of the prior art of record. Applicant requests a prompt allowance of all claims.

Respectfully submitted,

For: Eric James WALL et al.

By: 

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